

REMARKS

This paper is filed in response to the Office Action dated October 2, 2003 (hereafter, the "Office Action"). This paper is timely filed as it is accompanied by a petition for an extension of time to file in the second month and a check covering the requisite small entity extension fee.

Claims 5-10, 19-23, 34, 35, and 37-39 are pending in this application and remain at issue.

The Office Action notes that the rejections set forth in the Office Action dated December 2, 2002 have not been adequately addressed by the Applicants. In the Office Action dated December 2, 2002, claims 5-10, 19-24, and 32-39 were rejected under 35 U.S.C. §112, first paragraph, as assertedly not enabled; claims 5-10, 19, 21, 32, 33, 37, and 39 were rejected under 35 U.S.C. §102(b) as assertedly anticipated by Nordby *et al*; and claims 5-10, 19-23, 32-35, and 37-39 were rejected under 35 U.S.C. §103(a) as assertedly obvious over Nordby *et al*.<sup>1</sup>

The various bases for the claim rejections are addressed below in the order presented in the Office Action dated December 2, 2002. Reconsideration of the application, in view of the following remarks, is solicited.

*I. Claim Rejections - 35 U.S.C. §112*

Claims 5-10, 19-23, 34, 35, and 37-39 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement commensurate in scope with the claims. The Applicants respectfully traverse the enablement rejections.

While recognizing that the specification is "enabling for a method for extracting the crude epicuticular layer of plant or plant parts via exposure to a solvent (and the corresponding crude product obtained therefrom), wherein said exposure does not cause damage to layers under the epidermal layer of the plants or plant parts," the Examiner asserted that the specification "does not reasonably provide

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<sup>1</sup> With respect to the outstanding rejections, the Applicants note that claims 24 and 36 were canceled in Amendment "B," dated September 6, 2002. The Applicants also note that claims 32 and 33 were canceled in the Amendment dated May 16, 2003.

enablement for an antiviral substance *purified* from any of the plants as indicated in Claim 5 for example." *See* Office Action dated December 2, 2002 at page 3.

Additionally, while acknowledging that the Applicants have taught that antiviral preparations, for example, derived from pear, apple, grape, and tomato possess antiviral activity, the Examiner further asserted that the Applicants "have not clearly shown what parts of these plants were actually extracted to obtain an anti-viral substance." *See* Office Action dated December 2, 2002 at pages 3-4.

In the present case, the enablement inquiry properly focuses on whether the application reasonably teaches one of skill in the art to make preparations possessing antiviral activity from the cuticular and epicuticular layers of a plant or plant part, wherein the plant or plant part is selected from the group consisting of *apple and tomato*. The application teaches how to make preparations possessing antiviral activity by exposing a plant or plant part (having a cuticular or epicuticular layer) to a solvent under conditions sufficient to solubilize materials in the cuticular and epicuticular layers of the plant, while leaving cells and tissues internal to the epidermis substantially unaffected. The application further teaches how to use the claimed antiviral preparations in teaching how to evaluate the antiviral activity of the preparations. Given this level of instruction, the application-as-filed provides sufficient guidance to enable the claimed subject matter.

The Applicants respectfully submit that the antiviral preparations are derived from the cuticular and epicuticular layers of a plant or plant part, not a plant or plant part *per se*. It is the Applicants' discovery of anti-viral compounds in the cuticular and epicuticular layers of a wide variety of plants and plant parts, as disclosed in the application-as-filed, that led to the Applicants' invention. Thus, the Applicants have disclosed that the antiviral compounds are found in (1) the cuticular and/or epicuticular layers of (2) a variety of plants, and (3) parts thereof. Any experimentation necessary to practice the claims, which recite *a plant or plant part selected from the group consisting of apple and tomato*, would be minimal and, more importantly, routine. Moreover, the specification specifically identifies exemplary plant parts having a cuticular or epicuticular layer, such as fruits, flowers, leaves, roots, stems, and bark, and that such plant parts contain anti-viral substances in their

cuticular and epicuticular layers. *See* the present application at page 8, lines 23-29. Thus, the facts of this case do not support the assertion that undue experimentation would be required to practice the full scope of the invention.

An analysis of the *Wands* factors supports the Applicants' assertion that the application enables the full scope of the claimed methods. With respect to the quantity of experimentation required, the Applicants respectfully submit that any experimentation needed to practice the claimed invention would amount to *routine screening* in view of the amount of guidance provided in the present disclosure. Furthermore, the Applicants have disclosed several working examples that provide additional guidance for practicing the claimed invention drawn to methods for producing antiviral preparations of *apple or tomato* plants or plant parts. For example, *see* the present application at Tables 1 & 2, and Figures 1 & 2. With respect to the state of the art, the Applicants submit that the art of screening preparations for antiviral activity had developed to such an extent that screening methods *per se* were routine as of the effective filing date. A related factor, the skill in the art, also favors a finding that the application enabled the full scope of the claimed subject matter insofar as the skill level in the biotechnology arts is relatively high, as noted by the CAFC in *Wands*. *See Wands*, 858 F.2d at 740.

For these reasons, the rejection of claims 5-10, 19-23, 34, 35, and 37-39 under 35 U.S.C. §112, first paragraph, for lack of enablement, should be withdrawn.

**II. *Claim Rejections - 35 U.S.C. §102(b)***

Claims 5-10, 19, 21, 37, and 39 stand rejected under 35 U.S.C. §102(b) as anticipated by Nordby *et al.*, J. Agric. Food Chem. 39: 957-962 (1991) (hereinafter "Nordby"). The Applicants respectfully traverse.

It is well established that each and every limitation of a claimed invention must be present in a single prior art reference in order for anticipation to be found. The standard for anticipation is one of strict identity. This standard has not been satisfied with respect to the claims as currently presented.

Nordby discloses an analysis of a grapefruit epicuticular wax composition, and that changes in the epicuticular wax composition that are induced by cold storage may

lead to the fruit being affected by a "chilling injury." Nordby does not disclose or suggest a method for producing any type of preparation from the epicuticular or cuticular layers of a plant or plant part, including the complete failure to disclose or suggest an anti-viral preparation as recited by the pending claims. Accordingly, Applicants respectfully submit that Nordby fails to disclose, suggest, or appreciate a method for producing a preparation possessing antiviral activity comprising substances obtained from cuticular or epicuticular layers of any plant or plant part, let alone the *apple or tomato* plants or plant parts recited by the pending claims. Because each and every limitation of the claimed invention is not present in Nordby, the reference does not anticipate the subject matter of any pending claim and the rejection of claims 5-10, 19, 21, 37, and 39 under 35 U.S.C. §102(b) should be withdrawn.

Moreover, grapefruit is not a member of the Markush group set forth in claim 5. Because each and every limitation of the claimed invention is not present in Nordby, the anticipation rejection of claims 5-10, 19, 21, 37, and 39 should be withdrawn.

*III. Claim Rejections - 35 U.S.C. §103(a)*

Claims 5-10, 19-23, 34, 35, and 37-39 stand rejected as obvious in view of Nordby. Applicants respectfully traverse.

Nordby fails to disclose, suggest, or *appreciate*, a method for producing a preparation possessing antiviral activity comprising substances obtained from cuticular or epicuticular layers of a plant or plant part. At best, Nordby *merely* discloses that increases in the concentrations of certain compounds that are naturally present in the epicuticular layer of grapefruit protect the fruit from chilling injury. There is simply no disclosure in Nordby that relates to antiviral properties. Nordby therefore does not disclose or suggest a method of producing an antiviral preparation as claimed.

For these reasons, the obviousness rejections of claims 5-10, 19-23, 34, 35, and 37-39 should be withdrawn.

*IV. Conclusion*

It is respectfully submitted that this application is now in condition for allowance. Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, she is respectfully invited to contact the undersigned attorney at the indicated telephone number.

Respectfully submitted,

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